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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/081,301

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Rebecca E. Cahoon

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10/15/2003

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EXAMINER

HUTSON, RICHARD G

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 10/15/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/081,301

Applicant(s)

CAHOON ET AL.

Examin r

Richard G Hutson

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-16 and 18-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13 and 18-27 is/are rejected.
- 7) ☒ Claim(s) 14 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- ☐ Interview Summary (PTO-413) Paper No(s). _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Applicants amendment of the specification and the cancellation of claim 17, Paper No. 12, 8/8/2003, is acknowledged. Claims 11-16 and 18-27 are at issue and are present for examination.

Claim Objections

Claims 14 and 15 are objected to because of the following informalities:

Claims 14 and 15 are each dependent on rejected claim 11. Applicants have respected clarification "as claim 11 is rejected, not canceled." Applicants comments regarding "cancelled" claims are confusing. Applicants are reminded that claims 14 and 15 were objected to for depending from a rejected claim, not a cancelled claim. Applicants appear to further question this previous objection of claims 14 and 15 because they depend from rejected claim 11 on the basis that all of the remaining pending claims also depend from claim 11, however only claims 14 and 15 are objected to. The reason for the objection only to claims 14 and 15 is because otherwise these claims are deemed allowable, however, the remaining pending claims which also depend from claim 11 (i.e. claims 12, 13 and 16-27) were not objected to, in addition to claims 14 and 15, because these claims were also included in the rejected of claim 11.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-13 and 16-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide that encodes a pyridoxamine-phosphate oxidase comprising the amino acid sequence of SEQ ID NO: 10, does not reasonably provide enablement for any polynucleotide that comprises a polynucleotide which encodes a polypeptide having 80% sequence identity to the amino acid sequence of SEQ ID NO: 10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection was originally made for claims 11-13 and 16-27. In response to this rejection applicants have cancelled claim 17 and traverse the rejection as it applies to claims 11-13, 16 and 18-27.

Applicants submit a copy of Notheis et al. (BBA, Vol 1247, pp 265-271, 1995) which discloses the purification and characterization of the pyridoxal-5'-phosphate:oxygen oxidoreductase (PNPox) from *E. coli* and an alignment of the claimed sequence with *E. coli* PNPox. Applicants submit that since instantly disclosed SEQ ID NO: 10 and the *E. coli* sequence share 40% identity, one of skill in the art would have appreciated that many variants sharing at least 80% sequence identity to SEQ ID NO: 10 would have been expected to retain PNPox activity. Applicants further submit the reference by diSalvo (JMB Vol 315, 385-397, 2002) which they submit supports the above by elucidation of active site structure of the *E. coli* PNPox.

Applicants argument is not found persuasive for the following reasons. While given applicants disclosure of SEQ ID NO: 10 and the *E. coli* sequence of Notheis et al., and a comparison of these sequences which reveals 40% identity, one of skill in the art may have appreciated that many variants sharing at least 80% sequence identity to SEQ ID NO: 10 would have been expected to retain PNPOx activity, however, applicants have not given any guidance as to **which** of those sequences which share 80% sequence identity would retain PNPOx activity, nor have applicants given any guidance as to how to make the majority of those variants having 80% sequence identity which maintain PNPOx activity. As previously stated, The specification does not support the broad scope of the claims which encompass any polynucleotide which encodes any pyridoxamine-phosphate oxidase having the 80% amino acid sequence identity to SEQ ID NO: 10, because the specification does not establish: (A) regions of the protein structure which may be modified without effecting pyridoxamine-phosphate oxidase activity; (B) the general tolerance of pyridoxamine-phosphate oxidases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue of a cold-active pyridoxamine-phosphate oxidase with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain the pyridoxamine-phosphate oxidase activity, as encoded by the polynucleotide claimed and the fact that the relationship between the sequence of a peptide and its

tertiary structure (i.e. its activity) are not well understood and are not predictable (e.g., see Ngo et al. in *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref: U, Form-892), it would require undue experimentation for one skilled in the art to arrive at the majority of those polynucleotides of the claimed genus which encode a polypeptide having the claimed pyridoxamine-phosphate oxidase activity.

Applicant is reminded that the disclosure taught by di Salvo et al. (JMB Vol 315, 385-397, 2002) of the active site structure of the *E. coli* PNPox is not available as a means of enabling applicants invention at the time of filing.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those polynucleotides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Richard G. Hutson', with a horizontal line extending to the right.

Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rg
10/10/2003